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10/553,671	10/17/2005	Valerie Bicard-Benhamou	MERCK-2686-2	1527

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EXAMINER

BLAKELY III, NELSON CLARENCE

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4131

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05/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,671	Applicant(s) BICARD-BENHAMOU ET AL.	
	Examiner NELSON C. BLAKELY III	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/05/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 33 is/are rejected.
- 7) ☒ Claim(s) 3,5,7,9-11,13-15,17,18,21 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's Amendment filed 03/05/2008 has been received and entered into the present application. 2. Claims 1-33 are pending. Claims 1-32 are amended. Claim 33 has been added pursuant Applicant's Amendment, filed 03/05/2008. Claims 29-32 are drawn to a non-elected group, thus claims 1-28 and 33 are under consideration for examination.

Lack of Unity

Applicant's election **with traverse** of an antimicrobial pigment obtainable by agitating a suspension, said pigment comprising one or more inorganic pigments and silver oxide as an antimicrobial compound in the reply filed on 03/05/2008 is acknowledged by the Examiner. The traversal is on the ground(s) that unity of invention for the combination of an independent claim to a product, a process specially adapted for manufacturing the product, and the use of the product does not require a technical feature that defines a contribution over the prior art. Applicant's traversal has been carefully considered in its entirety, but is not found to be persuasive because the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Therefore, by the reasons above and those made of record at pages 2-8 of the previous Office Action on 02/14/2008, the requirement is still deemed proper and is therefore made **FINAL**. Claims 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/05/2008.

Objections

Specification

The disclosure is objected to because of the following informalities:

Applicant's Amendment filed 03/05/2008 recites the relation to co-pending application Serial No. 10/553,668, filed 10/17/2005, and that both co-pending applications claim the benefit of priority to U.S. Provisional Application Serial No. 60/463,726, filed 04/18/2005; however, said application, '726, was filed 04/18/2003, not 04/18/2005.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claims

Claims 3, 5, 7, 9-11, 13-15, 17, 18, 21, and 28 are objected to because of the following informalities:

1. In claim 3, line 3 it appears that the term "pasta" is meant to be "paste".
2. Regarding claims 3, 5, 7, 9-11, 13-15, 17, 18 and 21, Applicant is encouraged to use proper Markush group language. For instance, in line 2 of claim 3, the transitional phrase "...formulation selected from the group consisting of..." should be used in lieu of "...formulation is in the form of...".
3. On line 2 of claim 28, it appears that "on" of the phrase "...at least on photostabiliser..." is meant to be "one".
4. On line 3 of claim 5, it appears that the term "alkines" is meant to be "alkynes".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "derivatives" in these claims render the claims herein indefinite. The recitation(s), "derivatives" is not clearly defined in the specification. The 10th edition of the Merriam-Webster's Collegiate Dictionary defines "derivative" as "a chemical

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substance related structurally to another substance and theoretically derivable from it.” Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to “derivatives” herein. One of ordinary skill in the art would clearly recognize that derivatives of the disclosed compounds of instant claim 5, or cellulose derivatives of instant claim 33 would read on any of those compounds having any widely varying groups that possibly substitute the compounds. Thus, it is unclear and indefinite as to how the “derivative” herein is encompassed thereby.

Furthermore, on line 3 of claim 5 the phrase “a formulation wherein said compound is...with or without functional groups...” is unclear. A compound as simple as CH₃ (an alkane, also of instant claim 5), wherein the hydrogens (H) comprise a function, would be considered a compound with a functional group. Therefore, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired to a compound “without functional groups”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo *et al*, U.S. Patent No. 6,030,627 (Cited by Applicant) in view of Seo *et al*. (Cosmetics & Toiletries®, Vol. 112, pages 83-90; 1997; Cited by Applicant; Article provided by Examiner), and Iler, U.S. Patent No. 2,885,366, as evidenced by Aleksandrov *et al*. (Translated from Atomnaya Énergiya, Vol. 48, No. 4, pages 252-253; 1980).

Applicant claims a formulation comprising pigment particles obtainable by agitating a suspension comprising one or more inorganic pigments and silver oxide, in

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order to reduce undesirable side-effects caused by microorganisms. Applicant claims in claims 6-17 that the inorganic pigments are platelet-, spherical-, or needle-shaped effect pigments that are based on the substrate, synthetic mica, for example, whereby the substrate is coated with alternating layers of selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, namely titanium dioxide, wherein a dopant is additionally included. Applicant discloses on page 3, line 30 through page 4, line 4 of the instant specification that effect pigments are those based on substrates which can be additionally coated with one or more layers of selectively or nonselectively absorbing or nonabsorbing metal oxides, for example. Applicant also claims that said inorganic pigment comprises spherical particles of metal oxides, wherein said spherical particles are coated with one or more layers of selectively or nonselectively absorbing or nonabsorbing metal oxides, and said antimicrobial pigment is coated with a protective layer of silica. In claim 18, Applicant claims that said silver oxide is substituted by zinc oxide, for example.

In reference claim 1, Seo *et al*, U.S. Patent No. '627, teach an antimicrobial cosmetic pigment comprising inorganic cosmetic pigment, amorphous glassy coating layer of metal oxide having a lattice structure formed over the surface of said inorganic cosmetic pigment and antimicrobial metals or antimicrobial metal ions intercalated inside the lattice structure of said coating layer of metal oxides. Seo *et al*, U.S. Patent No. '627, disclose in reference claims 3 and 4 that said inorganic cosmetic pigment is one or more of mica or titanium dioxide, for example, and wherein said coating layer of metal oxide comprises silica alone, or silica as the main ingredient and one or more

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selected from zinc oxide or ferric oxide (a dopant required by instant claim 9), for example, required by instant claims 1,6-17. Seo *et al*, U.S. Patent No. '627, further disclose in reference claim 7 that said antimicrobial metal of said antimicrobial cosmetic pigment is selected from a group that consists of silver, copper, and zinc, which may be added as a metal oxide in powder form (page 7, lines 10-17 of the reference specification); therefore, silver oxide or zinc oxide, from the Election Requirement, may be used as the antimicrobial metal of instant claims 1, 6-18.

Seo *et al*, U.S. Patent No. '627, differ in that the reference fails to disclose whether the inorganic pigment is platelet-, spherical-, or needle-shaped as required by instant claims 6, 14 and 15.

Seo *et al* (Cosmetics & Toiletries ®) recite an antimicrobial inorganic pigment comprising mica and titanium dioxide, several metal oxides, such as silica, as an amorphous coating, a coating comprising at least 70% silica applied at 15% by weight, a dopant, namely iron oxide, and silver ions on page 84, column 2, lines 14-33. Applicant discloses that the coating comprises one or more layers of selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, namely titanium dioxide, arranged as alternating layers with a refractive index $n > 1.8$ and $n \leq 1.8$. Applicant, as part of the Election Requirement, elected titanium dioxide, which comprises a selectively absorbing, nonselectively absorbing or nonabsorbing metal oxide; however, Seo *et al* (Cosmetics & Toiletries ®) employs the use of several metal oxides, including silica, alumina, calcium carbonate, and sodium metasilicate, and a small quantity of iron oxide as an amorphous coating. Though Seo *et al* (Cosmetics &

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Toiletries ®) does not teach the use solely of alternating layers of titanium dioxide as a coating, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides are used to make up the coating of the antimicrobial pigment of instant claims 10-12.

Seo *et al* (Cosmetics & Toiletries ®) further incorporates the iron oxide as an inorganic colorant or element as the dopant required by instant claim 13.

Seo *et al* (Cosmetics & Toiletries ®) differ in that the reference also fails to disclose whether the inorganic pigment is platelet-, spherical-, or needle-shaped as required by instant claims 6, 14 and 15, or any substitution of the antimicrobial compound, silver oxide, by zinc oxide, for example, as required by instant claim 18.

Therefore, since Seo *et al* (Cosmetics & Toiletries ®) teach an antimicrobial inorganic pigment comprising an inorganic cosmetic pigment (i.e. mica), silver ions, and a metal oxide (i.e. titanium dioxide), coated with several metal oxides including silica and iron oxide, for example, but lacks disclosure for substituting silver ions for zinc oxide, a skilled artisan would envisage combining the work of Seo *et al*, U.S. Patent No. '627, who teach an antimicrobial cosmetic pigment comprising inorganic cosmetic pigment, amorphous glassy coating layer of metal oxide having a lattice structure formed over the surface of said inorganic cosmetic pigment and antimicrobial metals or antimicrobial metal ions, that may be substituted by zinc oxide, intercalated inside the lattice structure of said coating layer or metal oxides. It would have been obvious to one of ordinary skill in the art at the time of the invention because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Applicant claims that the protective coating layer of said antimicrobial pigment of instant claims 16 and 17 is that of silica. On column 1, lines 15-26, and Figs. 1-3, Iler teaches that products with an amorphous silica coating and a core of another solid material ordinarily assume the form of finely divided spheres, plates, or fibers (needle-shaped), satisfying the requirement of instant claim 6. Iler also discloses on column 3, lines 1-17 that typical cores are composed of metal oxides, such as titanium dioxide, whereas various varieties of mica comprise plate-like mineral silicates; therefore the use of metal oxides to coat the antimicrobial pigment would intrinsically take on the form of a spherical particle required by instant claims 14 and 15. Iler does not provide any teachings of a specific antimicrobial pigment, per se; however, the reference is intended to show evidence that products with an amorphous silica coating tend to form a shape of instant claim 6, and specifically, to show that metal oxides coated with silica take the form of a spherical shape as required by instant claims 14 and 15.

Furthermore, Applicant has elected synthetic mica as the substrate of instant claims 8-10. Seo *et al* (Cosmetics & Toiletries ®) disclose the use of mica as a substrate; however fails to disclose whether the mica used was that of natural or synthetic. Therefore, since Aleksandrov *et al* teach the precision measurements of the registration efficiency of natural mica (muscovite) and synthetic mica (fluorophlogopite), and subsequently determined the average efficiency of natural and synthetic mica to be $95.2 \pm 0.55\%$ and $95.6 \pm 0.4\%$, respectively, on page 258, lines 28-34, a skilled artisan would infer that natural and synthetic mica are functional equivalents.

Therefore, a skilled artisan would envisage, with a reasonable amount of success, the combination (See rationale above in the instant rejection) of the antimicrobial cosmetic pigment and antimicrobial inorganic pigments taught by Seo *et al*, U.S. Patent No. '627, and Seo *et al* (Cosmetics & Toiletries ®), respectively, as evidenced by Iler, who taught that metal oxides coated with silica submit to the form of a spherical shape, and Aleksandrov *et al*, who disclosed the functional equivalents of natural and synthetic mica. An ordinary skilled artisan would have had a reasonable expectation of successfully modifying the teaching of Seo U.S. Patent No. '627, as set forth above in the instant office action, such as by using synthetic mica in place of natural mica. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time of the invention because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 2-5, 19-28, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo *et al*, U.S. Patent No. 6,030,627 (Cited by Applicant) in view of Seo *et al*. (Cosmetics & Toiletries ®, Vol. 112, pages 83-90; 1997; Cited by Applicant; Article provided by Examiner), and Iler, U.S. Patent No. 2,885,366, as evidenced by Aleksandrov *et al* (Translated from Atomnaya Énergiya, Vol. 48, No. 4, pages 252-253; 1980) as applied to claims 1, 6-18 above, and further in view of Vollhardt, U.S. Patent No. 6,274,124, Lee *et al*., U.S. Patent No. 7,250,174, Wallace (British Journal of Nutrition, Vol. 50, pages 345-355; 1983), De Tommaso, WO2002/04012, and Scott *et al*., U.S. Patent No. 6,482,397.

Applicant's claims have been described above in the instant Office Action.

Applicant additionally claims said formulation in order to reduce undesirable side effects caused by microorganisms, whereby said undesirable side effects are caused by dandruffs, acne, and/or malodour, in the form of a cream, for example, further comprising a suitable substrate for microorganisms, namely proteins, preservatives, antimicrobial agents, antibiotics, namely vancomycin, one or more UV filters, at least one self-tanning agent, dyes and coloured pigments, at least one antioxidant, vitamins, skin-protecting or skin-care active ingredients, at least one photostabiliser, and at least one customary excipient selected from animal and vegetable fats, for example, in claims 1-5, 19-28, and 33.

In reference claim 1, Vollhardt discloses the method for imparting water resistance to or improving water resistance of a cosmetic or dermatological formulation comprising at least one cosmetic and/or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin of humans or animals comprising: adding a water resistance improving effective amount of 1,2-pentanediol, an emulsifier, to said formulation. Vollhardt further discloses an oil-in-water emulsion, or cream on column 3, line 51 through column 4, line 20 of the specification, and further discloses in claims 1-8, 11, 12, 16, and 17 wherein said formulation comprises at least one organic UV filter substance, a photostabiliser, namely 2-phenylbenzimidazole, at least one antioxidant, at least one antimicrobial compound, and at least one skin-protecting or skin-care active ingredient, a skin whitening compound, for example, as required by instant claims 3, 19, 22, 25, 27, and

28. Vollhardt also discloses in reference claims 4-6 that said formulation comprises coated or uncoated inorganic pigments, wherein the inorganic pigments comprise pigments of a metal oxide, namely titanium, zinc, iron, and the mixtures thereof, for example.

Vollhardt fails to teach the incorporation of a protein, preservatives, antibiotics, (e.g. vancomycin), a self-tanning agent, dyes or coloured pigments, vitamins, or at least one customary excipient, waxes, for example, required by instant claims 4, 5, 19-21, 23, 24, 26 and 33.

Lee *et al* teach a method for preserving cosmetic compositions wherein a preservative, paraben, for example, a vitamin, namely Vitamin E, and a wax, jojoba glaze, for example, as conventional ingredients of the emulsion as required by instant claims 19, 26, and 33, respectively. In instant claim 1, Applicant claims a formulation for topical applications of said pigment particles in order to reduce undesirable side effects caused by microorganisms; therefore, one of ordinary skill in the art, at the time of the invention, would envisage the incorporation of a method to preserve said topical formulation in order to extend the shelf-life of said formulation, for example.

As mentioned previously, Applicant claims the use of proteins, for example, as suitable substrates for microorganisms; however, Wallace recites that the use of radioactively-labeled proteins as substrates for the study of proteolytic activity of rumen microorganisms is not a new idea in the first paragraph of the Discussion on page 352; therefore, it is known that proteins are may serve as substrates for microorganisms as

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required of instant claims 4 and 5. Furthermore, Wallace recites on page 345 in lines 1 and 2 of the first full paragraph that the rates of digestion of different proteins by the rumen bacteria have been approached in several ways. Therefore, since proteins are known substrates for microorganisms, such as rumen, a skilled artisan would envisage the incorporation of suitable protein in a formulation comprising antibiotics and antimicrobial agents, for example, as a means of “attracting” said microorganisms in order for such adjuvants to inhibit or abolish the growth of said microorganisms.

De Tommaso discloses the use of the antibiotic vancomycin as an anhydrous pharmaceutical composition; wherein De Tommaso also teaches said composition for use in a cream for topical applications, see Example, pages 2 and 3, as required by instant claims 20 and 21. The use of antibiotics, such as vancomycin by De Tommaso, is conventional, and a skilled artisan, at the time of the invention, would envisage the incorporation of an antibiotic as a chemotherapeutic agent to inhibit or abolish the growth of microorganisms in a formulation.

Scott *et al* disclose the use of dihydroxyacetone (DHA) as a self-tanning agent in reference claims 1-3. Scott *et al* further disclose on page 1, lines 52-65 of the specification that though DHA is used as a widely accepted self-tanning agent, coloring agents are included in sunless tanning compositions to provide the applier the ability to more accurately assess where they have applied the compositions to their skin. Therefore, the self-tanning agent, dihydroxyacetone, and coloring agents that are requisite of instant claims 23 and 24 have been previously taught by Scott *et al*. Additionally, it would be obvious to one of ordinary skill in the art to use a self-tanning

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agent and coloring agents or dyes in a formulation to ensure even distribution of said formulation to the troubled area.

Therefore, one of ordinary skill in the art would envisage the use of, with a reasonable amount of success, the combination of the antimicrobial cosmetic pigment and antimicrobial inorganic pigments taught by Seo *et al*, U.S. Patent No. '627, and Seo *et al* (Cosmetics & Toiletries ®), respectively, in the form of a cream, for example, to reduce undesirable side effects caused by microorganisms. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include conventional cosmetically suitable adjuvants, including antibiotics, preservatives, and self-tanning agents, for example, in the formulation of a topical application from the combined teachings of Seo *et al*, U.S. Patent No. '627, and Seo *et al* (Cosmetics & Toiletries ®) because said adjuvants are routinely added to cosmetic formulations to obtain products that exhibit desirable properties during processing or use, which include reducing undesirable side effects caused by microorganisms, extending the shelf life of said formulation, and assurance of even application of said formulation, for example. Furthermore, it would have been prima facie obvious to a person of ordinary skill in the art to formulate a cosmetically acceptable composition into a conventional form because said conventional cosmetic form would reasonably be expected to have the greatest acceptance among consumers. A skilled artisan would have had a reasonable expectation of success upon the addition of conventional cosmetic adjuvants or the preparation of a conventional cosmetic form because the addition of suitable adjuvants and the preparation of a conventional cosmetic form are well within the skill of an

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ordinary artisan. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time of the invention because the combined teachings of the prior art is fairly suggestive of the claimed invention.

With respect to the instant rejection, it is noted that the references do not teach that the composition can be used in the manner of instant claim 2, wherein said undesirable side-effects caused by microorganisms are dandruffs, acne, and/or malodour. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such disclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not impart a structural difference, thus the intended use is not limiting.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/553,668 (Serial No. '668), in view of Park *et al*, U.S. Patent No. 6,372,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a formulation comprising pigment particles obtainable by agitating a suspension comprising one or more inorganic pigments and silver oxide, in order to reduce undesirable side-effects caused by microorganisms, and copending application, Serial No. '668, claims an antimicrobial pigment obtainable by agitating a suspension, said pigment comprising one or more inorganic pigments and silver oxide as an antimicrobial compound. Both the instant and copending applications recite pigment particles or an antimicrobial pigment comprising one or more inorganic pigments and silver oxide, wherein inorganic pigments are platelet-, spherical-, or needle-shaped effect pigments that are based on the substrate, synthetic mica, whereby the substrate is coated with alternating layers of selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, namely titanium dioxide, wherein a dopant is additionally included. Applicants, in both applications also claim that said inorganic pigment comprises spherical particles of metal oxides, wherein said spherical particles are coated with one or more layers of selectively or nonselectively absorbing or nonabsorbing metal oxides, said inorganic

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pigment is coated with a protective layer of silica, and that silver oxide may, in fact, be substituted by zinc oxide. The main difference between the instantly claimed subject matter and that of the conflicting claims lies in the functional language, i.e. statements of intended use, recited in each of the claimed sets. The instant application discloses that the formulation further comprises preservatives, antimicrobial agents, antibiotics, namely vancomycin, one or more UV filters, at least one self-tanning agent, dyes and coloured pigments, at least one antioxidant, vitamins, skin-protecting or skin-care active ingredients, and at least one photostabiliser. The instant application additionally discloses that the formulation is in the form of a cream, for example, which further comprises at least one customary excipient from animal and vegetable fats, for example. Though the subject matter of the instant application distinctly claims the use of said antimicrobial pigment, the independent claim 1 of the copending application, Serial No. '668, uses open language, i.e. comprising, which could include the additional requisite subject matter of the instant application. Additionally, Park *et al* disclose a cream composition for skin care comprising ceramides, for example. The Park *et al* reference simply serves to illustrate the fact that cream formulations are conventional topical applications in the art, and a skilled artisan would envisage topical applications via a cream, for example, as an alternate route of administration. Therefore, a provisional obviousness-type double patenting rejection with regard to claims 1-28 and 33 is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The specification is objected to.

Claims 1-33 are pending.

Claims 29-32 are withdrawn from consideration.

Claims 3, 4, 7, 9-11, 13-15, 17, 18, 21 and 28 are objected to.

Claims 1-28 and 33 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is (571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang or Janet Andres can be reached on (571) 272-0562 or (571) 272-0867, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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